isodose control®

K082530

5. 510(k) Summary as required by 21 CFR 807.92

5.1. Submitter of 510(k)

510(k) owner's name	:	Isodose Control BV
address	:	Maxwellstraat 16 6716 BX Ede The Netherlands
phone	:	+31 318 502950
fax	:	+31 318 502528
name of contactperson	:	Hub van de Bergh
e-mail	:	hvandebergh@isodosecontrol.com
date the summary was prepared	:	August 25, 2006

OCT 30 2008

5.2. Device

5.2.1. Device: Cervix Ring Applicator

Name of the device / trade or proprietary name: **Cervix Ring Applicator Set 45°**
Cervix Ring Applicator Set 60°

Common or usual name: Brachytherapy Ring Applicator
Classification name: Remote controlled radionuclide applicator system
(per 21 CFR section 892.5700 Product code JAQ)

5.2.2. Device: Trocar Needle Sets

name of the device / trade or proprietary name:
Ø 1.5mm (17Ga), needle set, 300mm trocar point
Ø 1.5mm (17Ga), needle set, 250mm trocar point
Ø 1.5mm (17Ga), needle set, 200mm trocar point
Ø 1.5mm (17Ga), needle set, 150mm trocar point
Ø 1.5mm (17Ga), needle set, 100mm trocar point

common or usual name: Brachytherapy interstitial needles
classification name: Remote controlled radionuclide applicator system
(per 21 CFR section 892.5700 Product code JAQ)

5.2.3. Device: Martinez Prostate Template

name of the device / trade or proprietary name: **Martinez Prostate Template Set**
common or usual name: Brachytherapy Prostate Template
classification name: Remote controlled radionuclide applicator system
(per 21 CFR section 892.5700 Product code JAQ)

5.2.4. Device: Bonvoisin Gerard Esophageal Applicator Set

name of the device / trade or proprietary name: **Bonvoisin Gerard Esophageal Applicator Set**
common or usual name: Brachytherapy Esophageal Applicator
classification name: Remote controlled radionuclide applicator system
(per 21 CFR section 892.5700 Product code JAQ)

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5.3. Legally Marketed Device(s)

The devices can be shown to be substantial equivalent to the legally marketed devices cited in the tables below.

5.3.1. Cervix Ring applicator

Device	Manufacturer	510(k) #
Standard CT/MR Applicator set, Ring CT/MR applicator	Nucletron corp	K983341
HDR CT compatible Split Ring Applicator	Mick Radio-nuclear Instruments, inc	K063382
HDR Tandem /Ring applicator with rectal retractor	Mick Radio-nuclear Instruments, inc	K011657

5.3.2. Trocar Needle sets

Device	Manufacturer	510(k) #
Proguide Needle set	Nucletron Corp	K060349
Interstitial Needles	Varian Medical Systems, Inc	K073133

5.3.3. Martinez Prostate template

Device	Manufacturer	510(k) #
Prostate Stepper Template Set	Nucletron Corp.	K003270
Cet Prostate Applicator Set	Nucletron Corp	K990990

5.3.4. Bonvoisin Gerard Esophageal Applicator Set

Device	Manufacturer	510(k) #
Varian Esophagus Bougie Applicator	Varian Medical Systems, Inc	K063815

5.4. Description of the Device

The following described medical instruments are brachytherapy applicators for use with the Flexitron Brachytherapy Afterloader. Brachytherapy applicators are commonly used to facilitate the placement and positioning of a radioactive source inside or near the patient in order to administer radiation therapy to cancerous tissue. Prior to treatment radiation X-ray markers are positioned into the applicator channel(s) in order to determine source dwell positions with the help of radiographic images as part of the brachytherapy treatment planning process.

5.4.1. Description Cervix Ring Applicator

The Cervix Ring Applicator is a tandem and ring brachytherapy instrument. The applicator consists of 2 separately placed ridged brachytherapy channels, i.e. 1 tandem (intrauterine tube) and a ring tube.
The Cervix Ring Applicator is used as a gynaecological intracavitary instrument to assist the positioning of a radioactive source under remote control (involving HDR or PDR Flexitron Remote Afterloader system), in order to administer radiation therapy to cervix and uterus carcinoma.

5.4.2. Description Trocar Needle Sets

The trocar Needles are straight ridged needles made out of stainless steel and have closed end sharp tip for skin and tissue perforation.
The Trocar Needles are used as interstitial brachytherapy instruments to assist the positioning of a radioactive source under remote control (involving HDR or PDR Flexitron Remote Afterloader system), in order to administer radiation therapy to tissue and organ carcinoma.

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5.4.3. Description Martinez Prostate Template Set

The Martinez Prostate template is to be used for HDR/PDR brachytherapy of the prostate gland. In order to administer brachytherapy to the prostate, needles are inserted interstitially into the prostate with the guidance of a prostate template. The prostate template can be mounted on an Ultra Sound probe stepper device in such a manner that the US grid coordinates projected over the images of the prostate are corresponding to the grid indication of the prostate template and its holder.

5.4.4. Description Bonvoisin Gerard Esophageal Applicator Set

The Bonvoisin Gerard Esophageal Applicator consists of a flexible tube with a tapered distal tip. This applicator tube is advanced through the mouth into the esophagus, the tapered distal tip gently dilitates the esophagus, in order to facilitate the placement of the applicator tube.
When the applicator tube is in position the tube is to be immobilised in relation to the patient's mouth with the accompanied fixation mask. For connection and treatment with the brachytherapy remote afterloader a separate flexible treatment catheter is provided in the set. The distal end of the treatment catheter is to be inserted into the applicator tube and the proximal end is to be connected to the afterloader device.
In order to fit different esophagus anatomy sizes and/or treatment requirements the applicator tube is provided in different diameter sizes, ranging in diameter from 5 mm to 20 mm.
Both the fixation mask and the treatment catheter can be applied to all applicator tube sizes.

5.5. Intended use of the Device

5.5.1. Intended Use Cervix Ring Applicator

The Cervix Ring Applicator is for gynecological HDR or PDR brachytherapy of cevrix, endometrium and vagina, to be used only by trained physicians. The Maximum implementation duration per treatment application is 28 days.

5.5.2. Intended Use Trocar Needle Sets

The intended use is interstitial HDR or PDR brachytherapy treatment, to be used only by trained physicians. The maximum implantation period of the needles is 28 days.

5.5.3. Intended Use Martinez Prostate Template Set

The Martinez Prostate Template Set is for assisting interstitial HDR or PDR brachytherapy of the prostate gland, to be used only by trained physicians. The Maximum application duration per treatment application is 28 days.

5.5.4. Intended Use Bonvoisin Gerard Esophageal Applicator Set

The Bonvoisin Gerard Esophageal Applicator is intended for HDR or PDR brachytherapy treatment of the esophagus, to be used only by trained physicians. The Bonvoisin Gerard Esophageal Applicator is to be used as an accessory in conjunction with the Flexitron brachytherapy afterloading device.
The maximum implementation duration per treatment application is 24 hours.

5.6. Technological characteristics of the devices compared to the predicate device

The described brachytherapy applicators have similar technological characteristics compared to the legally marketed predicate devices listed above.

All these devices are also considered to be brachytherapy applicator instruments and are accessories to a brachytherapy remote afterloading system.

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5.7. Substantial Equivalence

From the discussion in previous paragraphs it can be concluded that the brachytherapy applicator devices have similar technological characteristics compared to the legally marketed predicate devices listed in paragraph 5.2.4.

The differences between the brachytherapy applicator devices and predicate devices do not concern the basic principle of operation and usage nor does it adversely affect the safety or effectiveness of the device.

The intended uses of Cervix Ring Applicator Set, the Trocar Needle sets, the Martinez Prostate Template Set and the Bonvoisin Gerard Esophageal Applicator Set are the same as their mentioned corresponding predicate devices.

5.7.1. Conclusion Substantial Equivalence

The *Cervix Ring Applicator Sets* are substantial equivalent to the legally marketed predicate devices.

The *Trocar Needle Sets* are substantial equivalent to the legally marketed predicate devices.

The *Martinez Prostate Template Set* is substantial equivalent to the legally marketed predicate devices.

The *Bonvoisin Gerard Esophageal Applicator Set* is substantial equivalent to its legally marketed predicate device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Hub van de Bergh
Quality Assurance & Regulatory Affairs Officer
Isodose Control B.V.
Maxwellstraat 16, 6716 BX Ede
THE NETHERLANDS

OCT 30 2008

Re: K082530
Trade/Device Name: Applicators for Afterloading Brachytherapy: Cervix Ring Applicator, Trocar Needle Sets, Martinez Prostate Template, and Bonvoisin Gerard Esophageal Applicator Set
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radio-nuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: August 25, 2008
Received: September 2, 2008

Dear Mr. van de Bergh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

isodose control®

Indications for Use

510(k) Number (if known): K082530

Device Name: Applicators for Afterloading Brachytherapy:
- Cervix Ring Applicator
- Trocar Needle Sets
- Martinez Prostate Template
- Bonvoisin Gerard Esophageal Applicator Set

Indications for Use:

Brachytherapy applicators are commonly used to facilitate the positioning of a radioactive source inside or near the patient in order to administer radiation therapy to cancerous tissue.

Cervix Ring Applicator
The Cervix Ring Applicator is for gynecological Brachytherapy of cervix, endometrium and vagina, to be used only by trained physicians. The Maximum implementation duration per treatment application is 28 days.

Trocar Needle Sets
The intended use is interstitial HDR/PDR brachytherapy treatment, to be used only by trained physicians. The maximum implantation period of the needles is 28 days.

Martinez Prostate Template Set
The Martinez Prostate Template Set is for assisting interstitial HDR/PDR brachytherapy of the prostate gland, to be used only by trained physicians. The Maximum application duration per treatment application is 28 days.

Bonvoisin Gerard Esophageal Applicator Set
The Bonvoisin Gerard Esopheagel Applicator is intended for brachytherapy treatment of the esophagus, to be used only by trained physicians. The maximum implementation duration per treatment application is 24 hours.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082530

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